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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,661	09/08/2003	Ralf M. Luche	200125.408C2	3605

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,661	LUCHE ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45,46 and 50-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 45,46 and 50-55 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/03</u> . | 6) <input type="checkbox"/> Other: ____. |

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Claims 1-44 and 47-49 have been canceled. Claims 45, 46 and 50-55 are at issue and are present for examination.

Claims 45, 46 and 50-55 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 (upon which claims 46 and 50-55 depend) is unclear in the recitation of "relative to DSP-3" as it is unclear if the DSP-3 referred to is that of SEQ ID NO:2 or if it could be other proteins as well. For further examination it is presumed that this recitation referred to SEQ ID NO:2.

Claim 45, 46, and 50-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for substrate trapping mutations of amino acids 57 and/or 88 of SEQ ID NO:2, does not reasonably provide enablement for any substrate trapping mutant of any dual specificity phosphatase having 75% identity to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 45 is so broad as to encompass any substrate trapping mutant of any dual specificity phosphatase having 75% identity to SEQ ID NO:2 while claims 46, and 50-55 encompass substrate

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trapping mutants of any dual specificity phosphatase having 75% identity to SEQ ID NO:2 wherein at least one or both of positions 57 and/or 88 are modified. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of substrate trapping mutants broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and amino acid sequence of a single dual specificity phosphatase and 2 specific substrate trapping mutations thereof.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in

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any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any substrate trapping mutant of any dual specificity phosphatase having 75% identity to SEQ ID NO:2 or any substrate trapping mutants of any dual specificity phosphatase having 75% identity to SEQ ID NO:2 wherein at least one or both of positions 57 and/or 88 are modified because the specification does not establish: (A) regions of the protein structure which may be modified to reduce phosphatase activity without effecting substrate binding activity; (B) the general tolerance of dual specificity phosphatases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues of SEQ ID NO:2 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the

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claimed invention in a manner reasonably correlated with the scope of the claims broadly including any substrate trapping mutant of any dual specificity phosphatase having 75% identity to SEQ ID NO:2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of substrate trapping mutants having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Belmont et al. (US PGPUBS 2005/0014222) teach a human JNK activating phosphatase which has 92% overall identity to SEQ ID NO:2 of the instant application and is 100% identical to residues 1-169 of SEQ ID NO:2 (see Figure 1), and a catalytically inactive variant thereof in which Cys88 is replaced with serine (see paragraph 271. The Cys88Ser variant of Belmont et al. was first disclosed in application 60/155,068, filed on 9/21/99 however the instant application is granted the benefit of the filing date of provisional application 60/142,338 as the provisional and parent application 09/608,062 which was

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filed within 12 months of the filing of 60/142,338 provide support for the instant claims.

Birse et al. (WO 01/90304) and Hillman et al. (WO 00/06728) each teach a dual specificity phosphatase identical to SEQ ID NO:2 of the instant invention. SEQ ID NO:2811 of Birse et al. (first disclosed in 60/205,515, filed 5/19/00) and SEQ ID NO:27 of Hillman et al. are identical to SEQ ID NO:2 herein. Birse et al. is not provided with the instant action in view of the large size of the instant reference (over 2000 pgs in length).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Prouty
Primary Examiner
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